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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

7590 04/19/2005

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/3/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/3/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on February 3, 2005 is acknowledged. Claims pending and under consideration are claims 1-6 and 8-11. Claim 7 has been canceled and withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections Withdrawn

1. In view of applicant's response, the objection to the Information Disclosure Statement (page 2) has been withdrawn, as the application was submitted in accordance with 37 CFR 1.98 (a) (1).

2. In view of applicant's response, objections to the specification (page 2, paragraph 1) have been withdrawn.

3. In view of applicant's response, the objection to claim 7 has been withdrawn, as claim 7 has been canceled.

Objections Maintained

4. Objection to the Information Disclosure Statement is maintained for the reasons set forth on page 2. Applicant has submitted 1 of the 3 references that are missing. The two that have not been submitted have not been considered. Examiner is suggesting that in addition to sending the articles to the USPTO applicant should also fax the missing documents to the examiners Rightfax machine (571-273-2921).

Rejections Withdrawn

5. Claim rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement (page 3, paragraph 3) has been withdrawn upon further consideration by the examiner.

Rejections Maintained

6. The rejection of claims 1-6 and 9 and 1-6 and 10 under 35 U.S.C. 102(b) as being anticipated by Binder (U.S. Patent 5,670,484 and EP 0 845 267 B1) are maintained for the reasons set forth in the previous Office Action page 11, paragraph 4 and page 13, paragraph 5.

The rejection was on the ground that Binder discloses (1) a method for mitigating or inducing remission of a skin lesion associated with a cutaneous cell-proliferation disorder in a mammal comprising administering a therapeutically effect amount of a

Botulinum toxin in a pharmaceutically safe form to the mammal by delivery of the Botulinum toxin to the site of the lesion. (2) The method according to claim 1 wherein the Botulinum toxin is administered by subcutaneous injection. (3) The method according to claim 1 wherein the Botulinum toxin is Botulinum toxin A (column 9, line 13). Binder shows that Botulinum toxin A has the ability to reduce the number, severity and/or frequency of appearance of lesions and associated discomfort experienced by the patient suffering from primary cutaneous disorders such as psoriasis and dermatitis (column 4, line 10). Discomfort is defined as: state of physical unease: very mild pain or a feeling of being physically uncomfortable (Encarta® World English Dictionary [North American Edition] © & (P) 2004 Microsoft Corporation. Binder further teaches the serotypes of Botulinum toxin B, C1, C2, D, F and G (column 2, line 43). Additionally, Binder teaches a preferred administration of individual dosages of about 5-15 units (column 5, line 39).

The rejection was on the ground that Binder teaches an invention relates to the use of a neurotoxin for a medicament treating cutaneous cell-proliferate disorders. Specifically, the invention comprises the use of a therapeutically effective and pharmaceutically safe neurotoxin. The medicament will preferably be for the subdermal or sub-cutaneous administration, but may also be used for topical and transdermal routes of administration (page 3, section 0016, line 30). Binder shows the preferred neurotoxin of the invention is Botulinum toxin A (page 3, section 0018, line 38). Additionally, Binder shows the target tissue for administration of a neurotoxin according to the invention is skin. "Skin" as used on the disclosure shall refer to the tissue comprised of epidermal, dermal, subdermal and subcutaneous layers of cells (page 3, section 0019, line47). Lastly, Binder teaches that the method of the invention can be expected to be effective in mitigating lesions (e.g., by reducing their size or incidence) (page 5,section 0035, line 27).

Applicant urges that a) Binder does not even contain any of the words: warts, corns, calluses, neuromas, ulcers, hammertoes and bunions, b) Binder discloses that the conditions being treated are psoriasis, dermatitis, eczema, and pyriatis rosea. These conditions are caused by excessive cell proliferation and c) Binder does not disclose, teach, or even suggest treatment of a skin disorder comprising warts, corns, calluses, neuromas, ulcers, hammertoes or bunions. As these conditions are associated with cell proliferation.

It is the examiner's position that Binder discloses lesions. Lesions are being viewed as being an equivalent of ulcers. In the specification Applicant characterizes a stage one ulcer as a reddening of skin, where the redness does not go away when the pressure is relieved (page 2). Binder discloses that lesions may be comprised of elevated papules, reddish erosions and/or pustules (column 1, line 30). Contrary to what applicant says Binder discloses cutaneous cell-proliferative disorders (e.g. psoriasis, dermatitis, and forms of pityriasis, such as pitiyriasis rosea, pityriasis rosacea and pityriasis rubra (column 5, lines 24-26)). These are all examples of what skin disorders are, which does not mean that those are the only skin disorders for which the invention can encompass. Lastly, there is no specific exclusion to that of cell proliferative disorders. The claims as they have been presented are that of a Markush group, thus the examiner is viewing ulcers as the lesion disclosed in Binder.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 6, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Binder (U.S. Patent 5,670,484).

Claims 6, 8 and 11 are drawn to a method for treating a skin disorder, the method comprising a step of administering between about 1 unit and about 3,000 units of botulinum toxin to a location of a skin disorder of a patient, wherein the skin disorder comprises a disorder selected from the group consisting of warts, corns, calluses, neuromas, ulcers, hammertoes and bunions, thereby treating the skin disorder.

Binder discloses (1) a method for mitigating or inducing remission of a skin lesion associated with a cutaneous cell-proliferation disorder in a mammal comprising administering a therapeutically effect amount of a Botulinum toxin in a pharmaceutically safe form to the mammal by delivery of the Botulinum toxin to the site of the lesion, (2) The method according to claim 1 wherein the Botulinum toxin is administered by subcutaneous injection, (3) The method according to claim 1 wherein the Botulinum toxin is Botulinum toxin A (column 9, line 13). Binder shows that Botulinum toxin A has the ability to reduce the number, severity and/or frequency of appearance of lesions and associated discomfort experienced by the patient suffering from primary cutaneous disorders such as psoriasis and dermatitis (column 4, line 10). Discomfort is defined as: state of physical unease: very mild pain or a feeling of being physically uncomfortable (Encarta® World English Dictionary [North American Edition] © & (P) 2004 Microsoft Corporation. Binder further teaches the serotypes of Botulinum toxin B, C1, C2, D, F and G (column 2, line

43). Additionally, Binder teaches a preferred administration of individual dosages of about 5-15 units (column 5, line 39). Binder has the same method steps and the same end point as that of Applicant. Inherently, the method of Binder would treat a wart.

8. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. Patent Application Publication 2004/0087893 A1).

Claim 11 is drawn to a method for treating a wart, the method comprises the step of administering a therapeutically effective amount of a botulinum toxin to a wart thereby treating the wart.

Kwon disclose a method of administering a safe and efficient amount of botulinum toxin for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses and bunions (page 6, section 0077). The specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

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